Complete Summary

GUIDELINE TITLE

Premature rupture of membranes.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Premature rupture of membranes. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1998 Jun. 10 p. (ACOG practice bulletin; no. 1). [70 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2004, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Premature rupture of membranes in pregnancy

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention

CLINICAL SPECIALTY

Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the current understanding of premature rupture of membranes (PROM) and to provide management guidelines that have been validated by appropriately conducted outcome-based research

TARGET POPULATION

Pregnant women with suspected premature rupture of membranes

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. History and physical examination including sterile speculum examination and visualization of amniotic fluid in the posterior vaginal fornix or clear fluid passing from the cervical canal
2. pH of the vaginal sidewalls or fluid pool
3. Ultrasound examination
4. Assessment of fetal presentation and gestational age
5. Fetal heart rate monitoring to assess fetal status
6. Assessment of group B streptococcal status and the need for intrapartum prophylaxis
7. Assessment of fetal pulmonary maturity

Management

1. Induction of labor (32 to 36 weeks of gestation)
2. Expectant management (stable condition and less than 30 to 32 weeks of gestation) including modified bed rest, periodic assessment for maternal infection, fetal surveillance, counseling women presenting before presumed fetal viability
3. Tocolysis
4. Prophylactic antibiotics (intravenous ampicillin and erythromycin followed by oral amoxicillin and erythromycin OR intravenous ampicillin followed by oral amoxicillin OR intravenous ampicillin/sulbactam followed by oral amoxicillin/clavulanate)
5. Antenatal corticosteroids

MAJOR OUTCOMES CONSIDERED

- Risk factors associated with premature rupture of membranes (PROM)
- Rate of maternal and fetal complications associated with PROM
- Infant survival rates in pregnancies complicated by PROM

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between 1980 and August 1997. The search was restricted to articles published in the English language. Priority was given to the articles reporting results of original research although review articles and commentaries also were consulted. Abstracts of research presented at symposiums and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and ACOG were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, the recommendations are provided and graded according to the following categories:

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final

guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- With term premature rupture of membranes (PROM), labor may be induced at the time of presentation or patients may be observed for up to 24 to 72 hours for the onset of spontaneous labor.
- Antibiotics prolong the latency period and improve perinatal outcome in patients with preterm PROM and should be administered according to one of several published protocols if expectant management is to be pursued prior to 35 weeks of gestation.
- Antenatal corticosteroids should be administered to gravidas with PROM before 32 weeks of gestation to reduce the risks of respiratory distress syndrome, neonatal intraventricular hemorrhage, necrotizing enterocolitis, and neonatal death.
- Digital cervical examination should not be performed in patients with PROM who are not in labor and in whom immediate induction of labor is not planned.
- Patients with PROM prior to 30 to 32 weeks of gestation should be managed conservatively if no maternal or fetal contraindications exist.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Tocolysis may be utilized in patients with preterm PROM to permit administration of antenatal corticosteroids and antibiotics.
- Antenatal corticosteroids may be administered to gravidas with PROM up to 34 weeks of gestation.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Improved understanding and management of premature rupture of membranes (PROM)

Specific Benefits

- Corticosteroid use in women with PROM prior to 30 to 32 weeks of gestation reduces respiratory distress syndrome. The benefit of antenatal corticosteroids may outweigh the risk in patients between 24 and 32 weeks of gestation.
- Antibiotic therapy in patients with preterm PROM have been shown to prolong pregnancy and reduce chorioamnionitis, postpartum endometritis, pneumonia, intraventricular hemorrhage, and perinatal morbidity including neonatal sepsis, respiratory distress syndrome, and necrotizing enterocolitis.

POTENTIAL HARMS

Because of the possible adverse fetal effects and possible effects on maternal immune status of repeated weekly courses of antenatal corticosteroids, the repeated doses should only be given on an as needed basis.

QUALIFYING STATEMENTS

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These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Jun (reviewed 2004)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 14, 2005.

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